

CLAIMS

We claim:

1. A method comprising the step of using a specific heparan sulfate glycosaminoglycan antibody identified herein as PTI-HS7 to diagnose the presence of amyloid deposits, or Parkinson's disease, in a human patient.  
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2. A method for diagnosing an amyloid disease, or a susceptibility to an amyloid disease, in a patient, the disease related to the levels of a PTI-HS7 antigen, the method comprising the step of testing with a PTI-HS7 antibody for elevated levels of PTI-HS7 antigen in the patient, whereby any elevated levels of PTI-HS7 antigen are indicative of the presence, susceptibility to, or progression of, the amyloid disease in  
10 the patient.
3. The method of claim 2 wherein the amyloid disease has an associated amyloid and the amyloid disease is selected from the group of amyloid disease associated with Alzheimer's disease, Down's syndrome, hereditary cerebral hemorrhage with amyloidosis of the Dutch type, the amyloid disease associated with type II diabetes, the amyloid disease associated with chronic inflammation, various forms of malignancy and Familial Mediterranean Fever, the amyloid disease associated with multiple myeloma and other B-cell dyscrasias, the amyloid disease associated with the prion diseases including Creutzfeldt-Jakob disease, Gerstmann-Straussler syndrome,  
15 kuru and animal scrapie, the amyloid disease associated with long-term hemodialysis and carpal tunnel syndrome, the amyloid disease associated with endocrine tumors such as medullary carcinoma of the thyroid, and the alpha-synuclein associated diseases including Parkinson's disease and Lewy body disease.  
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4. The method of claim 3 wherein the amyloid disease is associated with Alzheimer's disease.  
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5. The method of claim 3 wherein the associated amyloid is beta-amyloid protein or A $\beta$ , AA amyloid or inflammation-associated amyloid, AL amyloid, amylin or islet amyloid polypeptide, PrP amyloid, beta<sub>2</sub>-microglobulin amyloid, transthyretin or prealbumin, or variants of procalcitonin.  
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6. The method of claim 2 wherein the testing with the PTI-HS7 antibody uses a biological fluid of the patient.
7. The method of claim 6 wherein the biological fluid is selected from the group of fluids consisting of blood, plasma, serum, cerebrospinal fluid, sputum, saliva, urine and stool.

8. The method of claim 2 wherein the testing with the PTI-HS7 antibody uses a tissue section of the patient by standard immunohistochemistry.

9. A method for the treatment of a patient having an identified clinical need to interfere with the pathological effects of amyloid deposits, the method comprising the 5 step of administering to the patient a therapeutically effective amount of PTI-HS7 antibody.

10. A method for detection of amyloid disease in a human patient, the method comprising the step of using a radiolabeled PTI-HS7 antibody for radioimaging or *in vivo* diagnosis.

10 11. A method for detection and quantization of amyloid associated HS7 antigen in biological fluids comprising the steps of:

- a) binding an anti-PTI-HS7 monoclonal antibody to a microtiter well;
- b) blocking the microtiter well with Tris-buffered saline or the like containing detergent plus bovine serum albumin;
- c) adding to the well a quantity of biological fluid selected from the group of fluids consisting of cerebrospinal fluid, blood, plasma, serum, urine, sputum, saliva, urine and stool;
- d) incubating the biological fluid in the microtiter well to bind the antibody;
- e) adding to the microtiter well a second labeled monoclonal antibody against the same HS7 antigen but which is against a different epitope to bind to any HS7 protein captured by the first antibody;
- f) incubating with a substrate until a significant color reaction develops to detect antibody bound materials.

20 12. A method of treatment, prevention or management of an amyloidosis, or a disease related to alpha-synuclein, in a mammalian subject susceptible to, or afflicted by, the amyloidosis or alpha-synuclein disease, the method comprising the step of administering to the subject a therapeutic amount of PTI-HS7 antibody.

25 13. A method for diagnosing an amyloid disease in a subject, the method comprising the step of determining a level of PTI-HS7 antigen in a sample from the subject and comparing the level of PTI-HS7 antigen in the sample to normal levels, 30 wherein an increase in the level of PTI-HS7 antigen in the sample relative to normal indicates the amyloid disease.

14. A method for determining whether a subject is at increased risk of developing an amyloid disease, or diagnosing or prognosing the amyloid disease in the subject, or

monitoring a progression of the amyloid disease in the subject, the method comprising the steps of: a) determining a level of PTI-HS7 antigen in a sample from the subject; and b) comparing the level of PTI-HS7 antigen in the sample to a reference value representing a known disease or health status; thereby determining whether the 5 subject is at increased risk of developing the amyloid disease, or diagnosing or prognosing the amyloid disease in the subject, or monitoring the progression of the amyloid disease in the subject.

15. A method of evaluating a treatment for an amyloid disease, the method comprising the step of determining a level of PTI-HS7 antigen in a sample from a 10 subject under the treatment; and b) comparing the level of PTI-HS7 antigen in the sample to a reference value representing a known disease or health status; thereby evaluating the treatment for the amyloid disease.

16. The method of Claim 14, wherein the sample is a biological fluid, preferably cerebrospinal fluid.

15. 17. The method of Claim 14, wherein an increase of level of PTI-HS7 antigen in the sample from the subject relative to a reference value representing a known amyloid disease or health status indicates the diagnosis or prognosis, or progression, or increased risk of the amyloid disease.

18. The method of Claim 14 wherein the level of PTI-HS7 antigen in the sample is 20 detected and quantified using an immunoassay and/or a binding assay.

19. The method of Claim 14, wherein the reference value is that of a level of PTI-HS7 antigen in a sample from a subject not afflicted with the amyloid disease.

20. The method of Claim 14, further comprising comparing the level of PTI-HS7 antigen in the sample from the subject with a level of PTI-HS7 antigen in a series of 25 samples from the subject taken over a period of time.

21. A kit for determining increased risk of developing an amyloid disease, or diagnosing or prognosing the amyloid disease in a subject, or monitoring a progression of the amyloid disease in the subject, the kit comprising:

a) a reagent for detecting the presence or absence of PTI-HS7 antigen, the reagent 30 comprising PTI-HS7 antibody, and

b) instructions for determining increased risk of developing an amyloid disease, or diagnosing or prognosing the amyloid disease in a subject, or monitoring a progression of the amyloid disease in the subject by detecting and/or quantifying a level of PTI-HS7 antigen in a sample from a subject, and determining whether the

subject is at increased risk of developing the amyloid disease, or diagnosing or prognosing the amyloid disease in a subject, or monitoring the progression of the amyloid disease in the subject, wherein

a varied level of PTI-HS7 antigen in a sample relative to a reference value

5 representing a known disease or health status is indicates the increased risk of developing an amyloid disease, or the diagnosis or prognosis of the amyloid disease in the subject, or the progression of the amyloid disease in the subject.